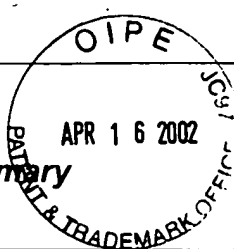


Office Action Summary

APR 16 2002



Application N .

09/762,602

Applicant(s)

KAROOUZAKIS ET AL.

Examiner

San-ming Hui

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

**COPY OF PAPERS
ORIGINALLY FILED**

- 1) ☒ Responsive to communication(s) filed on 15 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7, 10.
- ☐ Interview Summary (PTO-413) Paper No(s). _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

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Claims 6-26 are cancelled in the amendment filed January 15, 2002. Claims 27-47 are newly added in amendment filed January 15, 2002.

The outstanding rejections of claims 1-22 under 35 USC 112, first paragraph is withdrawn in view of the amendment filed January 15, 2002 to limit to the enabled misoprostol compounds. The amendment also avoids further rejection under 35 USC 112, first paragraph.

The outstanding rejections of claims 23-25 under 35 USC 102 is withdrawn in view of the amendments filed January 15, 2002 to limit the claims drawn to topical composition.

The outstanding rejection of claim 26 under 35 USC 112, 2nd paragraph is withdrawn in view of the cancellation of the claim.

The IDSs submitted December 7, 2002 and January 15, 2002 have been considered.

Claims 27-47 are pending.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In addition, claims 32-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for cyclodextrin, does not reasonably

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provide enablement for other agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Applicant fails to set forth the criteria that defines "an agent having beneficial effects". There is no biochemical, physical, or structural criteria provided in the specification to define what the agents might be. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of "agent having beneficial

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effects" examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "agent having beneficial effects", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-33, 38, and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 recites the limitation "an agent" in line 1. It is unclear what compounds are encompassed by the claims.

The expression "for achieving a beneficial effect in women..." in claim 43 renders the claim indefinite. "Beneficial" is a relative term. It is unclear what effects may be considered beneficial to a host encompassed by the claims.

The term "low" in claim 38 is a relative term which renders the claim indefinite. The term "low" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be

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reasonably apprised of the scope of the invention. It is unclear as to what degree of viscosity is encompassed by the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nahoum (US Patent 5,773,457) and Buyuktimkin et al. (US Patent 6,046,244) in view of El-Rashidy (US Patent 5,256,652), Lowrey (US Patent 5,981,563) and Reilly (chapter 80 in Remington: The Science and Practice of Pharmacy, page 1397, 1509-1512), references of record in the previous office action mailed May 23, 2001. Reasons for the rejection are essentially the same as that set forth in the previous office action mailed May 23, 2001.

Nahoum teaches that both misoprostol (a prostaglandin E₁ analog) and alprostadil (a prostaglandin E₁) are useful in treating female sexual dysfunction (See col. 9, lines 47-48; lines 53- col.10, line 1). Nahoum also teaches that the female sexual dysfunction treating composition, which may contain misoprostol, can be administered topically as gel, cream or ointment (See particularly col. 10, line 48-49). Nahoum also teaches that penetration enhancing agent may be incorporate into the female sexual

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dysfunction treating composition, which may contain misoprostol (See col. 14, line 8 - col. 15, line 48).

Buyuktimkin et al. teaches that a topical prostaglandin E₁ (PGE₁ also known as alprostadil) composition is useful for treating any disease that is treated by prostaglandin E₁ (see col.1, line 27-28 and col. 8, line 6-8). Buyuktimkin et al. also teaches the amount of the active prostaglandin ingredient to be 0.1-0.5 %w/v (See col. 10, Table 1).

The primary references do not expressly teach that the topical sexual dysfunction treating composition employs misoprostol or misoprostol and alprostadil in combination particularly. The primary references do not expressly teach that the amount of misoprostol to be 0.3-0.9%. The primary references do not expressly teach the application of the topical prostaglandin composition in a method of treating female sexual dysfunction to the vagina or clitoris. The primary references do not expressly teach the female sexual dysfunction treating method comprising α -cyclodextrin, gelatin, and hydroxymethylcellulose. The primary references do not expressly teach the female sexual dysfunction treating method comprising hydroxypropyl methylcellulose which comprises hydroxypropyl methylcellulose 3000 in the amount of 4% w/v.

El-Rashidy teaches a topical sexual dysfunction treating composition that comprises a vasodilating agent, α -cyclodextrin, and hydroxypropyl methylcellulose (See col. 3, line 67-68; col. 6, line 2-4). El-Rashidy also teaches that the amount of hydroxypropyl methylcellulose is 2-3%w/v (See col.8, Table II).

Lowrey teaches that the sexual response in females involve vasodilation and engorgement of the genitalia with arterial blood in a manner analogous to the male erectile response (See col. 5, line 38-51).

Reilly teaches that gelatin is useful as an emulsifying agent which can be utilized to formulate topical formulation (page 1397, col. 1; also page 1510 col.1, last paragraph).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to apply a topical female sexual dysfunction treating composition of misoprostol in the amount of 0.3-0.9% with or without the second vasoactive agent onto the vagina or clitoris. It would have been obvious for one of ordinary skill in the art at the time the invention was made to incorporate α -cyclodextrin, gelatin, and hydroxypropyl methylcellulose, which comprises hydroxypropyl methylcellulose 3000 in the amount of 4%, into the topical female sexual dysfunction treating composition in a method to treat female sexual dysfunction.

One of ordinary skill in the art would have been motivated to apply the sexual dysfunction treating composition, employing misoprostol in the amount of 0.3-0.9%, with or without another vasodilator, cyclodextrin, gelatin, and hydroxypropyl methylcellulose, which comprises hydroxypropyl methylcellulose 3000 in the amount of 4%, onto the vagina or clitoris in a method to treat female sexual dysfunction because these agents are known to be useful in the treatment of sexual dysfunctions, including in female. Furthermore, it is known in the art that female sexual response is associated with vasodilation and engorgement of the genitalia with arterial blood. Therefore applying a

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composition containing known vasodilating agents, including the instant compounds directly onto any area of the genital would have been reasonably expected to be effective in causing vasodilatation and engorgement of the genitalia; and thereby treating female sexual dysfunction. Furthermore, incorporating known topical pharmaceutical composition excipients such as cyclodextrin, gelatin, and hydroxypropyl methylcellulose such as hydroxypropyl methylcellulose 3000 (hydroxypropyl methylcellulose with a specific molecular weight) that are well known to be useful additives in forming topical compositions is considered within the skill of artisan.

Furthermore, optimization of result effect parameters (e.g., the amount of ingredients such as hydroxymethylcellulose and misopriostol) is obvious as being within the skill of the artisan, absent evidence to the contrary.

Claims 43-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nahoum (US Patent 5, 773,457).

Nahoum teaches that both misoprostol and alprostadil are useful in treating female sexual dysfunction (See col. 9, lines 47-48; lines 53- col.10, line 1). Nahoum also teaches that misoprostol and alprostadil may be formulated into topical composition and that the topical female sexual dysfunction treatment composition may contain carboxy methylcellulose (See particularly col. 13, line 46-48).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to incorporate misoprostol, carboxymethyl cellulose and a second vasodilating agent such as alprostadil into a pharmaceutical composition.

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One of ordinary skill in the art would have been motivated to incorporate misoprostol, hydroxypropyl methylcellulose and a second vasodilating agent such as alprostadil into a pharmaceutical composition because combining two or more agents which are known to be useful to treat sexual dysfunction individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069. Absent evidence to the contrary, no such evidence was seen to be present herein.

It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, there is no examples or clinical studies presented for the evaluation of unexpected effectiveness of the instant invention. Therefore, no convincing and clear unexpected result over the cited prior art is seen.

Response to Arguments

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208

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USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant's remarks filed January 15, 2002 regarding the each and every cited references not teaching all the references individually have been considered but are not found persuasive because this is a rejection under 35 USC 103 not 102. Therefore, each reference by itself has not been asserted to teach all the limitations recited in the claims herein and is not asserted to anticipate the claimed invention. The combined teachings of the cited prior art taken as a whole clearly renders the claimed invention obvious.

Applicant's remarks filed January 15, 2002 regarding Nahoum not teaching the advantages of misoprostol over alprostadil have been considered but are not found persuasive as to the non-obviousness of the claimed invention because advantages of misoprostol are not recited in the claims. Furthermore, regardless of any asserted advantages of misoprostol over alprostadil, Nahoum clearly teaches that both misoprostol and alprostadil are useful in treating female sexual dysfunction.

Applicant's remarks filed January 15, 2002 regarding Nahoum not disclosing how to treat female sexual dysfunction have been considered but are not found persuasive because Nahoum clearly teaches that the female sexual dysfunction treatment composition can be administered topically. Taken with the teaching of the other cited prior art, one of ordinary skill in the art would have reasonably expected that topical application of isoprostol to the clitoris and vagina would have been useful in the treatment of female sexual dysfunction, as discussed above in the rejection under 35 USC 103.

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Applicant's assertion filed January 15, 2002 that one of ordinary skill in the art might preferentially look to the 13 examples for guidance and since none of the 13 examples suggest the use of prostaglandins, no motivation for using prostaglandins for treating sexual dysfunction has been provided by Nahoum have been considered but are not found persuasive because again Nahoum clearly teaches both misoprostol and alprostadil are useful in treating female sexual dysfunction. Please note that the whole disclosure (not just the examples) of US Patent is considered as to motivation for the claimed invention and US Patents are presumed enabled and valid. Therefore, one of ordinary skill in the art would not only look at the examples for guidance.

Applicant's assertion filed January 15, 2002 that Buyumtkin et al. describes various techniques for increasing transdermal uptake of PGE1 to treat peripheral vascular disease in general have been considered but are not found persuasive because Buyumtkin et al. clearly teaches that PGE1, when administered topically, is useful in treating sexual dysfunction (See col. 8, line 6-8).

Applicant's remarks filed January 15, 2002 that Buyumtkin et al. suggests there were no effective topical compositions containing prostaglandin E1 have been considered but not found persuasive because the inventors of Buyumtkin et al. merely cited the problem which was solved by the patentees.

Applicant's remarks filed January 15, 2002 that Buyumtkin et al. not seeking to demonstrate an effective amount of a prostaglandin to be topically administered. Applicant further remarks that Buyumtkin et al. is directed specifically and only to increase the amount of the compound that can cross the skin. These remarks have

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been considered but are not found persuasive because Buyumtkin et al. clearly teaches the resulting topical composition is useful in treating sexual dysfunction, as discussed above, also please see Buyumtkin et al., col. 8, line 6-8. Therefore, one of ordinary skill in the art would reasonably expect those amounts of PGE1, which are demonstrated in the example to be useful in the treatment of sexual dysfunction.

Applicant's remarks filed January 15, 2002 that El-Rashidy teaches the use of topical compositions of isoquinoline ethers for treatment of male impotence have been considered but are not found persuasive because contrary to applicant's assertion, El-Rashidy not only teaches isoquinoline ether, but also vasodilators such as α -adrenergic blocker for treating male impotence topically (See claim 8). Further, these remarks are not seen to be relevant to the basis of rejection under 35 USC 103 set forth in the previous office action mailed May 23, 2001. It is the Examiner's position that El-Rashidy clearly teaches a topical sexual dysfunction treating composition that comprises a vasodilating agent, α -cyclodextrin, and hydroxypropyl methylcellulose, which is in the amount of 2-3%w/v (See col.8, Table II and col. 3, line 67-68; col. 6, line 2-4).

Applicant's remarks filed January 15, 2002 that El-Rashidy does not teach that cyclodextrin would have beneficial effects have been considered but are not found persuasive because cyclodextrin is recited in the claims as the agent which would possess the beneficial effects herein. Please note that products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical

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structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Applicant's assertion filed January 15, 2002 that Lowery does not suggest how a therapeutic agent for treating sexual dysfunction might be administered to a female patient who suffers from sexual dysfunction have been considered but are not found persuasive because the remarks are not seen to be relevant to the basis of the rejection under 35 USC 103 set forth in the previous office action mailed May 23, 2001. Lowery teaches that vasodilation and engorgement of the genitalia with arterial blood is involved in sexual excitement in females. Therefore, one of ordinary skill in the art would reasonably expect the employment of a vasodilating agent onto the female genitalia to sexually excite a female, and treat sexual dysfunction thereby.

Applicant's remarks filed January 15, 2002 regarding topical and intra-urethral application of compounds not being effective in treating male sexual dysfunction have been considered but are not found relevant to the basis of the rejection under 35 USC 103 set forth in the previous office action mailed May 23, 2001. The teaching of the cited prior art clearly renders the topical female sexual dysfunction treatment method and composition herein obvious.

Applicant's remarks filed January 15, 2002, regarding Rielly not teaching or suggesting gelatin to be used in the claimed invention have been considered but are not formed persuasive because Rielly clearly teaches that gelatin is useful in formulating a topical composition due to gelatin's usefulness in emulsions.

Applicant's remarks filed January 15, 2002 regarding Exhibit B, the clinical data of topical treatment of male sexual dysfunction using misoprostol and Alprostadil have been considered but not found persuasive because the data are seen to be irrelevant to the basis of rejection under 35 USC 103 since the data are directed to male sexual dysfunction treatment instead of female sexual dysfunction treatment.

Applicant's remarks filed January 15, 2002 regarding Exhibit C, a press release reporting the disappointing effect of Topiglan have been considered but are not found persuasive because Exhibit C (published in 2001) is published after the filing date of the instant application. Obviousness is evaluated as of the time the invention was made. Furthermore, Exhibit C is not seen to be relevant to the basis of rejection under 35 USC 103 set forth in the previous office action mailed May 23, 2001 since Topiglan is a different topical composition than the topical composition of the instant claimed invention. Other than the fact that both compositions are administered topically, the two products are totally different. For example, the instant claimed invention is for treating female sexual dysfunction whereas Topiglan is for treating male sexual dysfunction. Moreover, the active ingredient of the instant claimed invention comprises misoprostol whereas the active in Topiglan is alprostadil only. Furthermore, the precise formulation of the composition of Topiglan is not known from the disclosure of Exhibit C. Therefore, it is not clear to one of ordinary skill in the art whether the efficacy of Topiglan is the closest standard for comparison for female sexual dysfunction treatments. Thus, the significance of this reference in overcoming any grounds of rejection herein as to the topical female sexual dysfunction treatment composition herein is not seen.

Response to the Declaration by Mr. Fotinos

Fotinos' opinion statements in the Declaration, paragraph 4, filed January 15, 2002 that the pharmacological activity of topically applied misoprostol was substantially superior to other prostaglandins in particular, alprostadil in the treatment for male erectile dysfunction have been considered but are not found persuasive as to the nonobviousness of the instant claimed invention because the data are seen to be irrelevant to the basis of rejection under 35 USC 103 since the data are directed to male sexual dysfunction treatment instead of female sexual dysfunction treatment as claimed herein.

Fotinos' statements in the Declaration, paragraph 5, filed January 15, 2002 regarding Exhibit C disclosing Topiglan, a topical alprostadil composition for male erectile dysfunction, being underscored by disappointing results in male erectile dysfunction clinical studies have been considered but not found persuasive because Exhibit C (published in 2001) is published after the filing date of the instant application. Obviousness is evaluated as of the time the invention was made. Furthermore, Exhibit C is not seen to be relevant to the basis of rejection under 35 USC 103 set forth in the previous office action mailed May 23, 2001 since Topiglan is a different topical compositions than the topical composition of the instant claimed invention. Other than the fact that both compositions are administered topically, the two products are totally different. For example, the instant claimed invention is for treating female sexual dysfunction whereas Topiglan is for treating male sexual dysfunction. Moreover, the

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active ingredient of the instant claimed invention comprises misoprotol whereas the active in Topiglan is alprostadil. Furthermore, the precise formulation of the composition of Topiglan is not known from the disclosure of Exhibit C. Therefore, it is not clear to one of ordinary skill in the art whether the efficacy of Topiglan is the closest standard for comparison for female sexual dysfunction treatments. Thus, the significance of this reference in overcoming any grounds of rejection herein as to the topical female sexual dysfunction treatment composition herein is not seen.

No clear and convincing unexpected result for the claimed invention is demonstrated in the declaration.

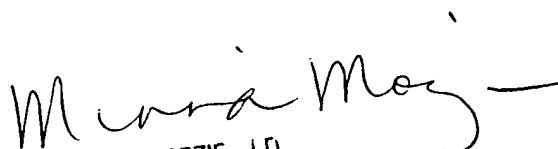
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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A handwritten signature in cursive script, reading "Minna Moezie", followed by a horizontal line.

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600